**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEBRASKA**

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| **DAVID DOYLE, et al.,** | ) | |
| | ) | |
| **Plaintiffs,** | ) | **8:06CV412** |
| | ) | |
| **vs.** | ) | **ORDER** |
| | ) | |
| **ELI LILLY & COMPANY,** | ) | |
| | ) | |
| **Defendant.** | ) | |

This matter is before the court on the defendant's Motion for Protection from Plaintiffs' 30(b)(6) Deposition Notice (Filing No. 83) and the plaintiffs' Motion for Leave to File Sur-Reply and Present Oral Argument (Filing No. 94). The defendant filed a brief (Filing No. 85), an index of evidence (Filing No. 84), a reply brief (Filing No. 92) and a reply index of evidence (Filing No. 93) in support of its motion. The plaintiffs filed a brief (Filing No. 88), an index of evidence (Filing Nos. 89-90) in opposition to the defendant's motion. The plaintiffs also filed a proposed sur-reply brief (Filing No. 94) and proposed index of evidence (Filing Nos. 94, 96 and 98) with their motion and in opposition to the defendant's motion.

After a telephone conference with counsel for the parties regarding the defendant's motion and in light of the urgency for resolution of the issues prior to the scheduled Rule 30(b)(6) deposition, the parties engaged in an abbreviated briefing period. After review of the parties' submissions, the court finds the plaintiffs' motion for leave to file a sur-reply should be granted. However, the court finds oral argument to be unnecessary. **See** NECivR 7.1(d).

## BACKGROUND

This case arises from the June 2, 2004 suicide of 9-year old Sean Doyle, the son or brother of the plaintiffs. **See** Filing No. 18 - Amended Complaint. The plaintiffs allege Sean Doyle hanged himself as a result of taking Strattera. ***Id.*** ¶ 1. Sean Doyle began taking the drug Strattera for Attention Deficit Hyperactivity Disorder in February 2004. ***Id.***

The plaintiffs' allege the defendant, who formulated, manufactured and marketed Strattera, knew or should have known that the use of Strattera could cause suicidal ideation and suicide in a percentage of users, prior to Starttera's approval for use by the Food and Drug Administration (FDA). ***Id.*** ¶¶ 12-13. However, the plaintiffs' allege the defendant failed to disclose such information to the FDA, physicians consumers or the general public prior to September 29, 2005. ***Id.*** ¶ 14.

On April 27, 2007, the plaintiffs served the defendant with a Rule 30(b)(6) deposition notice seeking testimony regarding 36 topics. **See** Filing No. 67 - Deposition Notice. The defendant objected to some of the topics and the parties engaged in attempts to resolve their disputes. After the parties' discussions, on June 13, 2007, the plaintiff served an amended deposition notice. **See** Filing No. 78. The parties are unable to resolve the discovery dispute related to six of the topic areas as follows:

> 5. Description of psychological side effects of Strattera including: suicidal ideation, suicide attempts, completed suicide, depression, impulsivity, anxiety, agitation, panic attacks, insomnia, irritability, hostility (aggressiveness), akathisia (psychomotor restlessness), hypomania, mania, emotional lability, mood swings, non accidental injury and hallucinations ("psychological side effects"), and including identifying when Lilly first had any notice whatsoever of such side effects.
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> 13. Lilly's compliance with the requirements of 21 C.F.R. § 201.57(e) to determine whether there was reasonable association of an assertion of a psychological side effect (as described above in paragraph 5) with Strattera based on the results of clinical trial and/or AERs prior to June 2, 2004.
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> 29. Any and all information regarding the science of linking antidepressant Paxil, and other pharmaceuticals such as Adderall and Concerta, to the possible risk of suicidality, suicidal ideation, suicide attempts and/or suicide and the relevance of this information to Strattera prior June 2, 2004.
> 30. When, why and how the issue of pediatric suicidal ideation, suicide attempt and/or suicide in individuals taking Prozac was first brought to Lilly's attention.

> 31. Whether Lilly suspected a casual link between the emergence of the following symptoms associated with Cymbalta—anxiety, agitation, panic attacks, insomnia, irritability, hostility (aggressiveness), impulsivity, akathisia (psychomotor restlessness), hypomania, mania and/or the emergence of suicidal impulses.
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> 33. Lilly's Case Report Forms (CRFs) involving a psychological side effect (as described above in paragraph 5) with Strattera based on the results of clinical trial prior to June 2, 2004.

**See** Filing No. 78.

## ANALYSIS

An order protecting disclosure or discovery is granted only upon a showing of good cause. **See** Fed. R. Civ. P. 26(c). The party seeking protection of information has the burden to demonstrate good cause for issuance of the order. ***Miscellaneous Docket Matter No. 1 v. Miscellaneous Docket Matter No. 2***, 197 F.3d 922, 926 (8th Cir. 1999). In order to make the requisite showing of good cause, the moving party must make "a particular and specific demonstration of fact, as distinguished from stereotype and conclusory statements." ***Gulf Oil Co. v. Bernard***, 452 U.S. 89, 102 n.16 (1981) (**quoting** 8 C. Wright & A. Miller, Federal Practice and Procedure § 2035, p. 265 (1970)); ***Miscellaneous Docket Matter***, 197 F.3d at 926. "Rule 26(c) confers broad discretion on the trial court to decide when a protective order is appropriate and what degree of protection is required." ***Seattle Times Co. v. Rhinehart***, 467 U.S. 20, 36 (1984); ***Roberts v. Shawnee Mission Ford, Inc.***, 352 F.3d 358, 362 (8th Cir. 2003). The court may issue a protective order to prevent or limit discovery where "justice requires to protect a party or person from annoyance, embarrassment, oppression or undue burden or expense." Fed. R. Civ. P. 26(c). The District Court "enjoys considerable discretion over discovery matters" and may limit the scope of discovery, if it has a good reason to do so. ***Burlington Ins. Co. v. Okie Dokie, Inc.***, 368 F. Supp. 2d 83, 86 (D. D.C. 2005).

Generally, parties may discover any relevant, unprivileged information that is admissible at trial or is reasonably calculated to lead to admissible evidence. **See** Fed. R. Civ. P. 26(b)(1). Relevancy is to be broadly construed for discovery issues and is not limited to the precise issues set out in the pleadings. Relevancy, for purposes of discovery, has been defined by the United States Supreme Court as encompassing "any matter that could bear on, or that reasonably could lead to other matter that could bear on, any issue that is or may be in the case." ***Oppenheimer Fund, Inc. v. Sanders***, 437 U.S. 340, 351 (1978). Discovery requests should be considered relevant if there is any possibility that the information sought is relevant to any issue in the case and should ordinarily be allowed, unless it is clear that the information sought can have no possible bearing on the subject matter of the action. **See *Burlington Ins.***, 368 F. Supp. 2d at 86. "All discovery requests are a burden on the party who must respond thereto. Unless the task of producing or answering is unusual, undue or extraordinary, the general rule requires the entity answering or producing the documents to bear that burden." ***Continental Illinois Nat'l Bank & Trust Co. of Chicago v. Caton***, 136 F.R.D. 682, 684-85 (D. Kan. 1991) (citation omitted). Typically, the burden is on the party resisting discovery to explain why discovery should be limited given that the Federal Rules allow for broad discovery. **See *Rubin v. Islamic Republic of Iran***, 349 F. Supp. 2d 1108, 1111 (N.D. Ill. 2004). However, the proponent of discovery must make a threshold showing of relevance before production of information, which does not reasonably bear on the issues in the case, is required. ***Hofer v. Mack Trucks, Inc.***, 981 F.2d 377, 380 (8th Cir. 1993). Mere speculation that information might be useful will not suffice; litigants seeking to compel discovery must describe with a reasonable degree of specificity, the information they hope to obtain and its importance to their case. **See *Cervantes v. Time, Inc.***, 464 F.2d 986, 994 (8th Cir. 1972).

The defendant seeks a protective order preventing discovery related to paragraphs 5, 13, 29-31 and 33 of the plaintiffs' amended Rule 30(b)(6) deposition notice. The defendant contends the notice is ambiguous, overly broad and seeks irrelevant information with regard to paragraphs 5 and 13, because the information sought is about medical events not mentioned in the plaintiffs' complaint. The defendant also contends the notice

topics contain an ambiguous phrase - "psychological side effects." The defendant argues paragraph 33 contains the same flaws as 5 and 13, but is also unduly burdensome because preparation for a deponent would include review of over 145,000 pages a detailed case report forms. The defendant asserts paragraphs 29-31 contain ambiguous terms, are overly broad and relate to irrelevant information about drugs which are not at issue in this matter, and in some instances not manufactured by the defendant. The defendant contends the plaintiffs have failed their burden of showing the deposition notice topics are reasonably calculated to lead to admissible evidence by being substantially similar to the issues raised in the plaintiffs' complaint.

**A. Psychological Side Effects**

The defendant argues it should be protected from discovery related to fifteen medical events not experienced by Sean Doyle. The defendant contends that since the plaintiffs' complaint notes only suicidality and suicidal ideation, the plaintiffs cannot establish other medical events, defined as psychological side effects by the plaintiffs, are likely to bear on issues in this lawsuit. The plaintiffs define certain alleged side effects of the use of Strattera as psychological side effects in paragraph 5 of the deposition notice. Although the plaintiffs may not be using the definition from a medical text, the defendant's ambiguity and overbreadth objections are overruled as the document as issue defines and limits the term.

The psychological side effects listed by the plaintiffs are "suicidal ideation, suicide attempts, completed suicide, depression, impulsivity, anxiety, agitation, panic attacks, insomnia, irritability, hostility (aggressiveness), akathisia (psychomotor restlessness), hypomania, mania, emotional lability, mood swings, non accidental injury and hallucinations." **See** Filing No. 78, ¶ 5. The defendant does not dispute the relevance of the first three listed side effects. Additionally, the defendant agreed, in a letter dated June 5, 2007, to have the deponent prepared to discuss depression, impulsivity and anxiety, as well. **See** Filing No. 84, Exhibit B.

The defendant contends the plaintiffs' "request to examine the details behind this laundry list of potential medical events amounts to a classic fishing expedition." **See** Filing

No. 85, p. 10. Further, the defendant contends the plaintiffs cannot possibly make a threshold showing of relevance for each event listed. ***Id.*** In response, the plaintiffs argue the relevance of the listed psychological side effects is logic. It logically follows, based on the evidence in this case and the defendant's own documentation that discovery into the psychological side effects is likely to lead to the discovery of admissible evidence. **See** Filing No. 94, p. 2-5. The plaintiffs provide evidence that Sean Doyle did experience unexplained fear, anxiety and psychological changes before his death. **See** Filing No. 94, Exhibits G and H. Additionally, the defendant has clinical trial reports which indicate when patients exhibited suicidal threats, statements or behaviors, such conduct was coded as "major depressive disorder," mood instability" and/or "agitation." **See** Filing No. 90, Exhibits A and B. Finally, the Strattera warning and prescribing information states under the heading "Suicidal Ideation":

> The following symptoms have been reported with STRATTERA: anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania and mania. Although a causal link between the emergence of such symptoms and the emergence of suicidal impulses has not been established, there is a concern that such symptoms may represent precursors to emerging suicidality. Thus, patients being treated with STRATTERA should be observed for the emergence of such symptoms.

**See** Filing No. 96, Exhibit D, p. 9.

On the basis of the evidence and argument presented by the plaintiffs, the court finds the plaintiffs have met their burden of showing the psychological side effects listed in paragraphs 5 and 13 reasonably bear on issues in this case and are likely to lead to the discovery of admissible evidence. For the same reason, paragraphs 5 and 13 are not overly broad in scope. The court finds the defendant has failed to meet its burden of showing protection from, or a limitation on, the discovery sought in paragraphs 5 and 13 is warranted.

**B. Drugs other than Strattera**

The plaintiffs' deposition notice seeks information related to the risk of suicide for drugs other than Strattera. **See** Filing No. 78, ¶¶ 29-31. Specifically, the deposition notice references "Paxil, and other pharmaceuticals such as Adderall and Concerta," Prozac, and Cymbalta. ***Id.*** The plaintiff contends the requested information is relevant to the defendant's knowledge that Strattera may cause suicidal ideation and suicidality.

The defendant contends the only drug taken by Sean Doyle was Strattera, therefore no other drug is relevant to this case. Additionally, the defendant contends the other drugs mentioned by the plaintiffs are different compounds, which have substantially different mechanisms of action. Specifically, the defendant states Strattera targets norepinephrine in the brain, whereas Paxil and Prozac target serotonin in the brain, and Cymbalta targets both norepinephrine and serotonin. The defendant states Concerta and Adderall are amphetamine-type substances which stimulate the central nervous system. Based on this information, the defendant contends such drugs are inherently unique in their impact on the human body. As such the drugs are not substantially similar to Strattera and the discovery sought by the plaintiffs would not be relevant to Strattera's alleged side effects.

The plaintiffs contend the category of antidepressants, such as the drugs listed above, are substantially similar making the information sought relevant to the defendant's understanding and notice of Strattera's risks for suicidality and suicidal ideation. The plaintiffs state the product warnings for Prozac, Cymbalta and Strattera are virtually identical. The plaintiffs also contend Prozac and Cymbalta, like Strattera are uptake inhibitors, making the drugs similar. However, the plaintiffs argue Cymbalta has more compositional similarities to Strattera than does Prozac because Cymbalta is a norepinephrine reuptake inhibitor.

Furthermore, the defendant objects to providing testimony about Paxil, Concerta and Adderall because those products are made by companies other than the defendant. **See** Filing No. 85, p. 5. The plaintiff does not make any arguments supporting discovery as to any one of these specific drugs, but argues the information is relevant to the defendant's understanding "about the science of linking antidepressants to the possible risk of suicidality and suicidal ideation prior to Sean's death." **See** Filing No. 88, p. 8.

The court finds the plaintiffs have failed to meet their burden of showing the requested discovery regarding Prozac, Paxil, and other pharmaceuticals such as Adderall and Concerta, reasonably bears on the issues in the case. While such drugs may be similarly classified as antidepressants, the plaintiffs have failed to show the drugs are substantially similar to the drug used by the decedent or how the drugs would put the defendant on notice of any anticipated side effects for Strattera. In contrast, the plaintiffs have met their burden of showing the drug Cymbalta is substantially similar to Strattera, to the extent that the defendant's understanding of the use and risks of Cymbalta may bear on the issues in this case. Accordingly, the plaintiffs have met their threshold burden of showing the relevance of paragraph 31 of the deposition notice, but have failed to do so with regard to paragraphs 29 and 30.

The defendant also objects to paragraph 31 on the basis that the language is overly broad, as discussed above, and ambiguous. Specifically, the defendant contends the language "casual link between the emergence of the following symptoms" is ambiguous and unintelligible even if the term casual is meant to be causal. **See** Filing No. 85, p. 7. Although the plaintiffs' deposition notice is not the model of clarity, the plaintiffs' explain that they seek information about whether certain alleged side effects of Cymbalta use may also be warnings a patient may be at risk for suicidal impulses. The side effects listed are a subset of the psychological side effects listed in paragraph 5 and associated with Strattera. Accordingly, the court finds the defendant has failed to sustain its burden of substantiating the objections or requiring protection from discovery related to paragraph 31 of the plaintiffs' deposition notice.

### C. Case Report Forms

The plaintiffs' deposition notice requests that the defendant make a representative available to testify regarding "Case Report Forms (CRFs) involving a psychological side effect (as described above in paragraph 5) with Strattera based on the results of clinical trial prior to June 2, 2004." **See** Filing No. 78, ¶ 33. The defendant objects as described above for paragraphs 5 and 13, but also contends the request is unduly burdensome. The defendant states there are over 145,000 pages of CRFs. Additionally, the CRFs contain

information for each person involved in the clinical trial such as blood pressure and heart rate for each visit. The defendant previously refused to produce the CRFs, stating all safety data is contained in the Clinical Trial Reports. The plaintiffs did not challenge the earlier refusal. The defendant contends the current deposition notice is more burdensome than a mere document request because of the breadth of knowledge a deposition designee would need.

The plaintiffs counter that the defendant's objection is inconsistent with the amount of documents already produced in this case. Further, the plaintiffs state the actual CRFs "may shed light on circumstances surrounding the onset of psychological side effects." This is so because the defendant's investigators may not have coded information as suicidal ideation or suicide-related, when the circumstances would be relevant to the instant case. Specifically, the plaintiffs provide examples such as a trial participant holding sharp objects to his head and stating "I want to be dead," but the situation was coded as experiencing "major depressive disorder" or "mood instability." **See** Filing No. 90, Exhibit A. The plaintiffs argue that based on this possibility of inexact information and the potential of the listed psychological side effects to lead to or be similar to suicide-related conduct, or notice to the defendant of such, the information sought is relevant.

It appears in the plaintiffs' briefing they seek the actual documents rather than merely to depose a knowledgeable representative. **See** Filing No. 88 - Plaintiffs' Opposition Brief p. 9 ("the Doyles seek Lilly's CRFs"). Such issue is not currently before the court. However, to the extent the plaintiffs seek to depose a representative who has actual knowledge of the details contained in the CRFs, the defendant's motion for a protective order must be granted. Any relevance of the information contained in the voluminous records cannot be meaningfully examined through a representative in a Rule 30(b)(6) deposition, at this time, particular because the plaintiffs cannot list a subset of subject CRFs. However, to the extent the plaintiffs seek to depose a representative about the general nature of the CRFs, the procedures used for coding or related training for the defendant's investigators related to topic as presented in paragraph 33, the plaintiffs may do so as such information is relevant to the issues raised by the plaintiffs and does not result in an undue burden, as described by the defendant. Upon consideration,

**IT IS ORDERED:**

1. The defendant's Motion for Protection from Plaintiffs' 30(b)(6) Deposition Notice (Filing No. 83) is granted in part and denied in part.

a. The defendant's motion is denied with regard to paragraphs 5, 13 and 31.

b. The defendant's motion is granted with regard to paragraphs 29 and 30.

c. The defendant's motion is denied, to the extent the plaintiffs seek to depose a representative about the general nature of the CRFs, the procedures used for coding or related training for the defendant's investigators related to topic as presented in paragraph 33. In all other respects, the defendant's motion is granted with regard to paragraph 33, not inconsistent with subparagraph (a) above.

2. The plaintiffs' Motion for Leave to File Sur-Reply and Present Oral Argument (Filing No. 94) is granted in part and denied in part. The plaintiffs' sur-reply brief and evidence is considered *instanter*. The plaintiffs' motion for leave to present oral argument is denied.

**ADMONITION**

Pursuant to NECivR 72.2 any appeal of this Order shall be filed with the Clerk of the Court within ten (10) days after being served with a copy of this Order. Failure to timely appeal may constitute a waiver of any objection to the Order. The brief in support of any appeal shall be filed at the time of filing such appeal. Failure to file a brief in support of any appeal may be deemed an abandonment of the appeal.

DATED this 9th day of July, 2007.

BY THE COURT:

s/ Thomas D. Thalken
United States Magistrate Judge